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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,961	04/16/2004	David R. Miller	022175-000200US	8211

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT	PAPER NUMBER
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3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/825,961	Applicant(s) MILLER ET AL.	
	Examiner Laura A. Bouchelle	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51, 53 and 56-63 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-8, 11-13, 15, 22-25, 29-33, 35, 36, 40-42, 45-47, 49, 53, 59, 60 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/7/06, 11/8/06</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3-5,9,10,14,16-21,26-28,34,37-39,43,44,48,50,51,56-58 and 61.

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DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 6, 7, 8, 11, 12, 13, 15, 22, 23, 25 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey et al (US 7,069,087) in view of Goltzer (US 4973305). Sharkey discloses a method for introducing substances into an intervertebral disc including all the elements and the steps set forth in the claims, except for anchoring the distal portion such that the distal portion remains anchored when the patient changes positions. Goltzer teaches a method for retaining an epidural catheter comprising the steps of inflating a balloon to anchor the distal end of the catheter in the desired location so that the catheter remains securely fixed in the desired location (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include the step of anchoring the distal end of the catheter in place as taught by Goltzer so that the patient can move without dislodging the catheter.

3. Claim 24, 53 differs from the teachings above in calling for the introduction of a placebo into the disc. It would have been obvious to one having ordinary skill in the art

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at the time the invention was made to use a placebo as the substance to be delivered, since Sharkey and Goltzer teaches that their methods/catheters are capable of delivering substances and could also deliver a placebo, and delivering a placebo is well known in the art.

4. Claim 25, 31, 32, 35, 3640-42, 45-47, 49, 60, 62, 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey in view of Goltzer as applied to claim 1 above, and further in view of Sluijter. Claim 25 differs from the teachings above in calling for the steps of causing the patient to assume a position where pain is experienced and introducing an anesthetic or analgesic into the disc. Sluijter teaches a method for treating back pain including the steps of inserting a catheter into the disc of a patient and introducing an anesthetic solution into the disc and observing the effect on the patient's pain (Col. 14, lines 12-13, 21-25). In this method, it is inherently disclosed that the patient has assumed a position where spinal pain is experienced because that would be a necessary step in determining the effect the treatment is having on the pain experienced. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method disclosed above to include the steps of having the patient assume a position in which back pain is experienced and introducing an analgesic into the disc as taught by Sluijter to that the effect of the treatment on back pain can be determined.

5. Claims 29, 30, 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey in view of Goltzer in view of Sluijter as applied to claim 25 above, and further in

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view of Diederich et al (US 2003/0216721). Claims 29 and 30 differ from the teachings above in calling for the step of performing a discography procedure. Diederich teaches performing a discography procedure to determine the discs to be treated and to monitor the progress of the treatment (Page 15, paragraph 0235, 0239). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method above to include the step of performing a discography as taught by Diederich to determine the discs to be treated and to monitor the progress of the treatment.

Response to Arguments

6. Applicant's arguments, see pages 13, 14, filed 10/4/06, with respect to the rejection(s) of claim(s) under Sharkey in view of Hoch have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Sharkey in view of Goltzer as above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
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LAB


KIMBERLY D. LUGGIESI
SUPERVISOR
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